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SUBJECT: PHILIPPINES ISSUES CHEAPER MEDICINES ACT IMPLEMENTING RULES
AND REGULATIONS

REF: A) Manila 497 B) Manila 2418

11. (SBU) Summary: The Philippine government recently issued implementing rules for the Cheaper Medicines Act, covering intellectual property, parallel importation, retail price controls, and labeling requirements on generic drugs. Local and foreign stakeholders remain skeptical that the law will reduce prices of medicines. Despite Post engagement with the Philippine departments and agencies that drafted the rules, there remain important USG concerns, especially on compulsory licensing, that were not addressed and that will require monitoring. End summary.

Released Implementing Rules to be Effective this Month

12. (U) The Philippine Department of Trade and Industry, Department of Health, the Intellectual Property Office, and the Bureau of Food and Drugs have jointly issued the implementing rules and regulations for the Cheaper Medicines Act that President Gloria Arroyo signed in June. The implementing rules include provisions that limit patent rights, facilitate the use of inventions by the government, ease restrictions on compulsory licensing, permit parallel imports, and require retail drug outlets to stock imported patented drugs and medicines. The rules also empower the Health Secretary to determine maximum retail prices for drugs and require generic medicines to bear a notice that "this product has the same therapeutic efficacy as any other generic product of the same name."

PHAP Active During the Public Hearings

13. (SBU) The Philippine government conducted seven public hearings in different parts of the country. The Pharmaceutical and Healthcare Association of the Philippines (PHAP), the representative of most pharmaceutical multinationals, was silent during the first public hearing (reftel A) but actively participated in subsequent hearings. Econoffs noted that some individual PHAP member firms like Sanofi Aventis, despite being members of PHAP, also made representations as individual companies. PHAP officials told Econoffs that PHAP also submitted position papers on the implementing rules.

Pfizer No Longer a PHAP Member

14. (SBU) According to PHAP, Pfizer left the association more than

two months ago. PHAP executive director Reinier Gloor explained that member firms of PHAP had different views on the medicine bill, and generally, PHAP adopted the view taken by the majority of its members. Pfizer, according to Gloor, had been in the minority on several recent issues and concluded that PHAP did not represent its views effectively. We did not notice Pfizer taking active part in the regulation process.

PHAP Supports Effective Implementation of New Medicine Law

15. (SBU) PHAP, despite having concerns regarding the implementing rules related to maximum retail prices, new use patents, generic labeling and parallel imports, issued a statement supporting implementation of the Cheaper Medicines Act. It thanked the Department of Health and Intellectual Property Office for the consultation process, and called the Act "a step towards attainment of an integral and comprehensive approach to health development." PHAP also reiterated its commitment to participate in healthcare reform initiatives.

Local Firms Take on Cheaper Medicines Law

16. (SBU) Econoffs met with officials of United Laboratories (Unilab), a Filipino-owned pharmaceutical firm operating throughout Southeast Asia that has a 20 percent share of the Philippine pharmaceutical market. Unilab CEO Carlos Ejercito was still concerned about the rules for maximum retail price, therapeutic efficacy and generic labeling, parallel importation, and patent infringement. Ejercito said that the cheaper medicines law will definitely not bring down medicine prices in the short term, and

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further reform would be necessary to bring prices down in the long term.

17. (SBU) According to Unilab Corporate Vice-President Joey Ochave, prices of medicines ought to come down in the next few years due to expiration of patents on "blockbuster" drugs, even without the new law. He said that over the next few years the generic market will be highly competitive as research companies, without many new blockbusters, are entering the generics markets in a big way. Unilab officials suggested that because of the public debate surrounding the Act, both industry and lawmakers have increased awareness of the importance of patents and trademarks to the pharmaceutical industry.

TRIPS Issues Remain

18. (SBU) Post continued its intensive engagement on the Act during the preparation of the implementing rules. Mission officials observed the public consultations that were held in Manila, and met separately with the Director General of the Intellectual Property Office, the Secretary of Trade and Industry, and representatives of the Department of Health. USTR supplied an analysis of initial drafts of the regulations, which we conveyed to our contacts. Unfortunately, several USG concerns were not ultimately addressed, including apparent TRIPS violations in both the Act and the rules in the provisions on compulsory licensing.

Comment: Minimizing Damage

19. (SBU) Our contacts in both the Legislative and Executive Branches have consistently maintained that they interpret the Philippine legislation as allowing full TRIPS compliance. We will monitor the implementation and lobby the GRP to implement the law in ways which respect TRIPS and the interests of U.S. companies.

KENNEY